NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS, U.S., INC., et al., **Movants,** **v.** **I/M/O LEVAQUIN PRODUCTS LIABILITY LITIGATION MDL PLAINTIFFS** **Respondent.**	**Civil Action No. 09-3272 (MLC)** **MEMORANDUM OPINION FILED UNDER TEMPORARY SEAL**

BONGIOVANNI, Magistrate Judge,

This matter comes before the Court upon Sanofi-Aventis, U.S., Inc. and Sanofi-Aventis, U.S., LLC's (collectively, "Sanofi-Aventis, U.S.") motion to quash five subpoenas *ad testificandum* and *duces tecum* issued by Respondent (the "MDL Plaintiffs"), the plaintiffs in the multi-district product liability litigation captioned *In re Levaquin Products Liability Litigation* (the "MDL Action"). The Court has fully reviewed and considered all papers submitted in support of and in opposition to Sanofi-Aventis, U.S.'s motion, and considers same without oral argument pursuant to FED.R.CIV.P. 78. For the reasons set forth more fully below, Sanofi-Aventis, U.S.'s motion to quash is granted in part and denied in part.

I. Background

The MDL Action is currently pending in the United States District Court for the District of Minnesota. In that action, the MDL Plaintiffs are pursuing products liability claims regarding the drug Levaquin, arguing that it causes tendon ruptures and that the defendants in the MDL Action (the "MDL Defendants") failed to warn users of Levaquin of this alleged dangerous

propensity. Levaquin is the brand name under which the drug levofloxacin is marketed in the United States by the MDL Defendants pursuant to their licensing agreement with Daiichi, a Japanese pharmaceutical company, and its New Jersey-based affiliate Daiichi Sankyo (collectively "Daiichi"), which own the patent for levofloxacin. Levofloxacin is a broad spectrum synthetic antibiotic used to treat various bacterial infections, including upper respiratory infections, urinary tract infections and prostatitis. (Sanofi-Aventis. U.S.'s Br. at 5; MDL Plaintiffs' Opp'n Br. at 3). Levofloxacin is part of a class of antibiotics known as fluoroquinolones. (MDL Plaintiffs' Opp'n Br. at 3).

The MDL Plaintiffs now seek to obtain discovery from Sanofi-Aventis, U.S. as well as from its foreign parent, Sanofi-Aventis, regarding studies performed by or on behalf of Sanofi-Aventis, U.S. discussing tendon disorders and their relationship to fluoroquinolones, communications with any European regulatory authority concerning tendon disorders as they relate to fluoroquinolones, communications with the MDL Defendants concerning tendon disorders as they related to fluoroquinolones and communications with Daiichi and affiliated companies concerning tendon disorders as they relate to fluoroquinolones. The MDL Plaintiffs also seek to depose the following individuals: (1) Wanju Dai, a current employee of Sanofi-Aventis, U.S.; (2) Lourdes Frau, a former employee of Sanofi-Aventis, U.S.; (3) Drew Levy, a former employee of Sanofi-Aventis, U.S.; and (4) Gaby Danan, a current employee of Sanofi-Aventis, who works in Paris, France.

Neither Sanofi-Aventis, U.S., nor Sanofi-Aventis is not a party to the MDL Action. Further, neither markets or sells Levaquin. Instead, Sanofi-Aventis holds the license to market

levofloxacin in Europe under the brand name Tavanic. Neither Sanofi-Aventis nor Sanofi-Aventis, U.S. markets Tavanic in the United States. (Sanofi-Aventis, U.S.'s Br. at 6).

Sanofi-Aventis, U.S. argues that the subpoenas issued by the MDL Plaintiffs should be quashed for several reasons. For example, Sanofi-Aventis, U.S. argues that the subpoenas should be quashed because the MDL Plaintiffs can obtain the subpoenaed information from a more convenient source and because the information sought is duplicative and cumulative of information already produced and to be produced. In this regard, Sanofi-Aventis, U.S. contends that the MDL Plaintiffs have apparently already obtained much of the information sought relating to communications with the European regulatory authority via information requests. As such, Sanofi-Aventis, U.S. claims that it would be unfair to require them to produce the same data to simply confirm its existence.

Sanofi-Aventis, U.S. also argues that the MDL Plaintiffs can obtain the information they seek from either the MDL Defendants, themselves, or from Daiichi, the owner of the levofloxacin patent and "the recipient of all data and documents from all of its marketing partners." (*Id*. at 17). Sanofi-Aventis, U.S. claims that both the MDL Defendants and Daiichi are in a better position than Sanofi-Aventis, U.S. to know what studies were conducted concerning levofloxacin and the MDL Plaintiffs' claim that levofloxacin causes tendon disorders. Indeed, Sanofi-Aventis, U.S. claims that "testimony about those studies as they relate to products marketed in the United States should obviously come from by [sic] a party to the MDL Action, rather than requiring Sanofi-Avetnis, U.S. to produce several of its employees and former employees as the MDL Plaintiffs demand." (*Id*. at 17-18). Sanofi-Aventis, U.S. notes that it does not have a license to market Levaquin in the United States and that it is not its "normal

business practice to maintain in the United States regulatory documents regarding products sold in Europe by its European parent or European affiliates." (*Id*. at 18). Further, Sanofi-Aventis, U.S. argues that the MDL Plaintiffs have already obtained significant discovery regarding the Ingenix Study, the study that is at the heart of the MDL Plaintiffs' subpoenas, from Ingenix and the MDL Defendants. For example, Sanofi-Aventis, U.S. claims that (1) Ingenix "***already provided*** the MDL Plaintiffs with documents related to the Ingenix Study"; (2) "the MDL Plaintiffs ***already deposed*** several Ingenix employees including the senior author and the chief physician who designed the Ingenix Study"; (3) "the MDL Plaintiffs ***already deposed*** two J&J employees who were involved in the Ingenix Study"' and (4) "J&J has ***already produced*** documents related to the study[.]" (Sanofi-Aventis, U.S.'s Reply Br. at 2 (emphasis in original)).

In addition, Sanofi-Aventis, U.S. argues that Daiichi, the owner of levofloxacin, was privy to and maintains all of the data that the MDL Plaintiffs seek from Sanofi-Aventis, U.S. In fact, Sanofi-Aventis, U.S. claims that pursuant to the applicable safety exchange agreement, if Sanofi-Aventis, U.S. needed to communicate something with the MDL Defendants, it would send the information to Daiichi, which would in turn communicate it to the MDL Defendants. Thus, Sanofi-Aventis, U.S. argues that Daiichi "is in the position to have the most knowledge about what is going on with the product across the world, including any inquiries by regulatory bodies." (Sanofi-Aventis, U.S.'s Br. at 19). Sanofi-Aventis, U.S. notes that the MDL Plaintiffs have served subpoenas on Daiichi and argues that they should await Daiichi's responses instead of seeking the same, duplicative information and testimony from Sanofi-Aventis, U.S. and Sanofi-Aventis. In this regard, Sanofi-Aventis, U.S. argues that by seeking the subpoenaed documents and testimony from Daiichi, "the MDL Plaintiffs can 'kill two birds with one stone' .

. . because [Daiichi's] representatives can testify about both the United States ***and*** European markets." (*Id*. (emphasis in original)). Further, Sanofi-Aventis, U.S. claims that Daiichi, as the owner of the patent for levofloxacin, would not only be in possession of communications between itself and Sanofi-Aventis, U.S., but also of communications that might have occurred between itself and the MDL Defendants. Again, Sanofi-Aventis, U.S. argues that requiring it "to locate and produce the same information that others will produce . . . constitutes the height of unnecessary cumulative and duplicative efforts and burdens." (*Id*. at 20). Sanofi-Aventis, U.S. similarly argues that the MDL Defendants can provide documents and testimony regarding communications with Johnson & Johnson through normal discovery mechanisms.

In addition, Sanofi-Aventis, U.S. contends that the subpoenas at issue should be quashed because the information sought is irrelevant. In this regard, Sanofi-Aventis, U.S. argues that the information sought by the MDL Plaintiffs, i.e. studies and communications regarding tendon disorders as they relate to fluoroquinolones, bears "no relation to the claims regarding Levaquin, which Sanofi-Aventis, U.S. does not market in the United States." (*Id*. at 22). Sanofi-Aventis, U.S. notes that it does not have a license to market Levaquin in the United States and claims that any studies that would have been performed would relate to the marketing of Tavanic in Europe by its foreign parent, Sanofi-Aventis. Sanofi-Aventis, U.S. claims that "why the MDL Plaintiffs need testimony or documents from [it] . . . regarding tendon disorders and their relationship to fluoroquinolones, as it relates to the European market, to prove their claims against the MDL Defendants, is suspect and rings more of a fishing expedition than targeted discovery[.]" (*Id*. at 22-23). Indeed, Sanofi-Aventis, U.S. claims that even if one assumes that Tavanic had similar side effects as Levaquin or that a European regulatory agency was investigating Tavanic in

Europe, that is of no relevance to the claims asserted by the MDL Plaintiffs in the MDL Action because "[t]o succeed on their claims against the MDL Defendants, the MDL Plaintiffs must show that the MDL Defendants knew or reasonably should have known that Levaquin was defective or unreasonably dangerous" and "[d]ocuments concerning Tavanic are . . . wholly irrelevant to the MDL Plaintiffs' claims regarding Levaquin." (*Id*. at 23). Further, Sanofi-Aventis, U.S. argues that any communications between it and any European regulatory authority (or testimony about same) is irrelevant "because the governmental agency responsible for approving and overseeing Levaquin . . . is the FDA." (*Id*.) Thus, Sanofi-Aventis, U.S. argues that "Europe is irrelevant to the MDL Action because the MDL Plaintiffs cannot rely on documents from European agencies regarding a drug marketed in Europe to prove by a preponderance of the evidence that Levaquin, which is sold only in the United States to consumers within the United States by the MDL Defendants, harmed anyone here." (Sanofi-Aventis, U.S. Reply Br. at 3).

In addition, Sanofi-Aventis, U.S. argues that the subpoenas should be quashed because it would be unduly burdensome for Sanofi-Aventis, U.S. to respond to same, especially in light of the fact that it has already complied with a previous subpoena. Sanofi-Aventis, U.S. notes that it "gratuitously cooperated" with a subpoena already issued to it by the MDL Plaintiffs. (*Id*. at 24). Sanofi-Aventis, U.S. claims that it spent significant time and money voluntarily complying with a subpoena issued to it by the MDL Defendants in July 2008. Indeed, Sanofi-Aventis, U.S. claims that in complying with the July 2008 subpoena, it conducted an "exhaustive search of its records and databases, produced documents, and provided Dr. Canabarro for deposition on February 26, 2009" and also voluntarily agreed to continue Dr. Canabarro's deposition for a

second day, despite being under no obligation to do so under FED.R.CIV.P. 30(d)(1). (*Id.*) Sanofi-Aventis, U.S. claims that, despite this compliance, it is now "being unduly burdened and harassed" by the MDL Plaintiffs through the issuance of the additional subpoenas. (*Id.* at 25).

In this regard, Sanofi-Aventis, U.S. claims that if it is required to comply with the subpoenas at issue, which span twelve years, then its "business operations would literally come to a halt to search for and gather documents from various sources, if those documents even exist, and identify personnel for their depositions." (*Id.*) Sanofi-Aventis, U.S. also notes that two of the subpoenas are directed to former Sanofi-Aventis, U.S. employees, both of whom Sanofi-Aventis, U.S. would have to locate and prepare. In addition, Sanofi-Aventis, U.S. argues that the MDL Plaintiffs not only seek documents from its employees, but also from an employee of its parent company, Sanofi-Aventis, which is located in France. Sanofi-Aventis, U.S. argues that the documents the MDL Plaintiffs seek from its parent "in Europe are not readily accessible because those documents are not maintained in a centralized location." (*Id.* at 26). Instead, Sanofi-Aventis, U.S. argues that each of its parent's affiliates "maintains its own regulatory filings, correspondence and other related documents" in its own respective European country. (*Id*). Thus, Sanofi-Aventis, U.S. argues that not only would it be unreasonably burdened if forced to comply with the subpoenas at issue but its European parent and affiliates in each European country would likewise be burdened. Indeed, Sanofi-Aventis, U.S. claims that requiring it "and its parent and European affiliates that market levofloxacin in European countries to locate, review and produce all communications and documents with countless European regulatory authorities, as well as copies of all studies, draft studies, protocols, drafts of protocols, internal and external communications on those topics . . . and raw and source data

regarding those studies and protocols, would cause incalculable and irrevocable burdens." (Sanofi-Aventis, U.S.'s Reply Br. at 9-10).

In addition, given the discovery it has already produced, including producing Dr. Canabarro for two depositions, Sanofi-Aventis, U.S. argues that it would be unreasonably burdensome for it to be forced to produce Drs. Levy, Danan, Frau and Dai for depositions. Sanofi-Aventis, U.S. claims that this is especially true given the fact that the MDL Plaintiffs seek Drs. Levy, Danan, Frau and Dai's deposition testimony "simply because they are either carbon-copied on or authored" email communications between Sanofi-Aventis, U.S., Daiichi, Ingenix and the MDL Defendants. (*Id*. at 10). Sanofi-Aventis, U.S. claims that Drs. Levy, Danan, Frau and Dai are not the only individuals that participated in the email communications in question. Instead "representatives of J&J and Ingenix ***that the MDL Plaintiffs have already deposed and from whom they have already obtained documents***" also participated in or were carbon-copied on the emails in question. (*Id*. (emphasis in original)). Sanofi-Aventis, U.S. argues that it "remains unclear why Sanofi-Aventis, U.S. should incur considerable, time and business disruption to search for and produce documents and representatives to testify about the Ingenix Study when, by their own admission to the MDL Court, the MDL Plaintiffs have already deposed the chief designer of the study and other representatives of Ingenix and J&J[.]" (*Id*. at 11).

Further, Sanofi-Aventis, U.S. argues that to the extent the Court permits certain depositions to go forward, the Court should nevertheless quash the subpoena to Dr. Dai who is the Associate Vice President and head of GPE Epidemiology at Sanofi-Aventis, U.S., Inc. In this regard, Sanofi-Aventis, U.S. contends that while "Dr. Dai was carbon-copied on emails and authored emails to J&J, Daiichi, Sanofi-Aventis, and her subordinates at Sanofi-Aventis, U.S. in

her capacity as an executive, she did not have direct daily responsibility for levofloxacin products." (*Id*. at 13). Indeed, Sanofi-Aventis argues that "Dr. Dai does not have direct and unique knowledge of the matters in dispute" and any information she could provide could also be provided by Dr. Levy. (*Id*. at 13-14). Consequently, given Dr. Dai's lack of "unique personal knowledge" of the information at issue, Sanofi-Aventis, U.S. argues that Dr. Dai, a "high-level executive[]" should not be compelled to testify. (*Id*. at 13).

In addition, Sanofi-Aventis, U.S. argues that the subpoenas should be quashed because they are overbroad. In this regard, Sanofi-Aventis, U.S. claims that the subpoenas, which seek at a minimum twelve years of information, are facially overbroad. Sanofi-Aventis, U.S. also claims that the subpoenas are "facially overbroad in that they seek information from Sanofi-Aventis, an entity that is based in Europe and over which Sanofi-Aventis, U.S. has no control." (Sanofi-Aventis, U.S.'s Br. at 27-28). Sanofi-Aventis, U.S. claims that as a separate entity and the mere subsidiary of Sanofi-Aventis, it "does not have the legal right or authority to demand the documents from" its parent. (*Id*. at 28).

Sanofi-Aventis, U.S. also contends that the subpoenas should be quashed for several procedural reasons. For example, Sanofi-Aventis, U.S. argues that the MDL Plaintiffs served one subpoena *ad testificandum* and *duces tecum* directed to two entities, namely itself and Sanofi-Aventis. Sanofi-Aventis, U.S. argues that "Sanofi-Aventis is a foreign company organized and existing under the laws of France, with its principal place of business in Paris" and that while Sanofi-Aventis, U.S. is one of Sanofi-Aventis' many subsidiaries, Sanofi-Aventis, U.S. "is a separate legal entity" and "is not authorized to accept or otherwise respond to a subpoena directed to or on behalf of Sanofi-Aventis." (*Id*. at 29-30). Accordingly, Sanofi-

Aventis, U.S. contends that the subpoena issued to Sanofi-Aventis should be quashed.

Sanofi Aventis, U.S. also argues that the subpoenas should be quashed because they violate various provisions of FED.R.CIV.P. 45. For example, the subpoenas at issue "seek to compel Sanofi-Aventis, Sanofi-Aventis, U.S., Gaby Danan, Lourdes Frau, Drew Levy and Wanju Dai - all non-parties to the MDL Action - to appear for depositions and produce documents in Minneapolis, Minnesota." (*Id*. at 30). Sanofi-Aventis, U.S. argues that in violation of Rule 45(c)(3)(A)(ii), Minnesota is greater than 100 miles from New Jersey where Sanofi-Aventis, U.S., Wanju Dai and, potentially, Lourdes Frau and Drew Levy are located and far greater than 100 miles from Paris, France where Sanofi-Aventis and Gaby Danan are located. Likewise, Sanofi-Aventis, U.S. contends that the subpoenas should be quashed because they violate the geographic restrictions set forth in Rule 45(a)(2) because the subpoenas were issued from this District but require "the provision of testimony and the production of documents in the District of Minnesota." (*Id*. at 31). Further, Sanofi-Aventis, U.S. argues that contrary to Rule 45(b)(1), which requires witness and mileage fees to be tendered, none of the subpoenas here were accompanied by witness and milage fees. Finally, Sanofi-Aventis, U.S. argues that to the extent this Court requires it to respond to the subpoenas at issue, then, pursuant to Rule 45(c)(1)'s obligation that a party serving a subpoena take measures to avoid imposing an undue burden or expense on the subpoenaed party, the MDL Plaintiffs should be forced to pay for the costs incurred by Sanofi-Aventis, U.S. in responding to same.

The MDL Plaintiffs oppose Sanofi-Aventis, U.S.'s motion to quash. With respect to the procedural deficiencies cited by Sanofi-Aventis, U.S., the MDL Plaintiffs argue that they have cured same and, therefore, Sanofi-Aventis, U.S.'s arguments concerning those deficiencies are

moot. Further, despite Sanofi-Aventi, U.S.'s arguments to the contrary, the MDL Plaintiffs claim that the information sought via the subpoenas is clearly relevant under FED.R.CIV.P. 26(b)(1) because it is "reasonably calculated to lead to the discovery of admissible evidence." In this regard, the MDL Plaintiffs argue that they have limited their requests to two primary areas of concern, namely information regarding tendon disorders and studies initiated at the request of European regulatory agencies that relate to fluoroquinolones, of which levofloxacin is one. The MDL Plaintiffs argue that "Sanofi, Daiichi and Johnson & Johnson constantly exchange information relating to levofloxacin - whether it be under the brand-name Levaquin or Tavanic." (MDL Pls.' Opp'n Br. at 13). Indeed, the MDL Plaintiffs argue that Levaquin and Tavanic "*are the same drug*, also known as levofloxacin." (*Id*. at 2 (emphasis in original)).

The MDL Plaintiffs claim that when levofloxacin was launched in Europe under the brand-name Tavanic, "it quickly became known, in Europe, as the most tendon toxic fluoroquinolone." (*Id*. at 5). As a result, the MDL Plaintiffs argue that the Medicines and Healthcare Products Regulatory Agency ("MHRA") of the United Kingdom requested that Sanofi-Aventis conduct a study regarding Tavanic and tendon toxicity. The MDL Plaintiffs contend that Sanofi-Aventis conducted two such studies, "which, though unpublished, found that levofloxacin was twice as tendon toxic as Cipro, another leading fluoroquinolone." (*Id*. at 6). The MDL Plaintiffs claim that "[t]he MHRA then requested that Sanofi-Aventis undertake a large-scale epidemiological study on levofloxacin and also proposed an interim update to the drug's warning label to declare that levofloxacin was, in fact, more tendon toxic than other fluoroquinolones." (*Id*.) The MDL Plaintiffs contend that as a result of this request, Sanofi-Aventis began organizing the requested study but out of concern that "changes to the European

labeling would lead to more stringent U.S. warnings and sales losses, [the MDL Defendants] proposed, funded, and co-authored the 'Ingenix Study,' which purportedly sought to analyze the risk of tendon rupture with fluoroquinolones." (*Id*.) The MDL Plaintiffs contend that "Sanofi employees in the United States were significantly involved in the process of designing and managing the Ingenix Study." (*Id*.) Given the fact that Tavanic and Levaquin are the same drug, i.e. levofloxacin, the MDL Plaintiffs argue that the information requested in the subpoenas is clearly relevant to their claims against the MDL Defendants regarding Levaquin.

Further, given Sanofi-Aventis, U.S., Sanofi-Aventis, Daiichi and the MDL Defendants' constant exchange of information pertaining to levofloxacin the MDL Plaintiffs claim that Sanofi-Aventis, U.S. should be compelled to respond to the subpoenas. The MDL Plaintiffs contend that while the protocol for exchanging information regarding levofloxacin may have directed Sanofi-Aventis, U.S. to communicate such information to Daiichi who would then communicate it to the MDL Defendants, such as Johnson & Johnson, testimony from Dr. Canabarro revealed that at times Sanofi-Aventis, U.S. communicated directly with Johnson & Johnson. In addition, the MDL Plaintiffs argue that discovery already produced reveals that "Daiichi itself chose to copy Johnson & Johnson and Sanofi employees on emails relating to levofloxacin." (*Id*. at 14). Further, the MDL Plaintiffs note that while Sanofi-Aventis, U.S. "[s]upposedly only marketed Tavanic[,]" Dr. Canabarro indicated that she maintained Levaquin files. (*Id*.)

The MDL Plaintiffs also contend that the subpoenas at issue are neither overly broad nor do they create an undue burden on Sanofi-Aventis, U.S. In this regard, the MDL Plaintiffs argue that they have "a significant need for the subpoenaed information as it will assist them in

discovering the genesis and configuration of the Ingenix Study, as well as how the results were analyzed." (*Id*. at 17). The MDL Plaintiffs further contend that the burden imposed on Sanofi-Aventis, U.S., if it is required to respond, would only be slight. The MDL Plaintiffs note that Sanofi-Aventis, U.S. has indicated that it would comply with the subpoenas to some extent. Further, they argue that Sanofi-Aventis, U.S. did not object to the Canabarro Subpoena, which required the production of

> All documents discussing the investigation of risks of tendonpathy in any Fluoroquinolone including Levaquin and Floxin by any European agency including but not limited to EMEA, French Pharmacovigilance, German, Belgium, Italian, and British authorities, during the time period January 2001 through December 2004. Such documents should include all internal an external documents, including all drafts thereof, handwritten notes thereon, and all e-mail communications.

(*Id*. at 17 (quoting McCormick Decl., Ex. B)).

In addition, the MDL Plaintiffs argue that the subpoenaed information cannot simply be obtained from the MDL Defendants or Daiichi. The MDL Plaintiffs note that Daiichi, like Sanofi-Aventis, U.S. is a third-party and can make the same arguments that Sanofi-Aventis, U.S. has made to deny the MDL Plaintiffs' access to the requested information. Further, the MDL Plaintiffs argue that there is no guarantee that the MDL Defenants have the documents requested in the subpoenas. Indeed, the MDL Plaintiffs argue that they "have learned that Johnson & Johnson's document retention policies are such that many of the documents the Defendants might have on these various subjects (including emails) have been destroyed in the normal course of business, so they are not available from Defendants." (*Id*. at 18). Thus, the MDL Plaintiffs claim that Sanofi-Aventis "is likely to have in its possession documents that Defendants (and/or

Daiichi) does not have, including documents that were not provided to or retained by Defendants, and communications between Sanofi and other nonparties, such as between European regulatory agencies and Sanofi." (*Id.*)

The MDL Plaintiffs also argue that given the size of Sanofi-Aventis, U.S. (its own website indicates that it is the fifth largest pharmaceutical company in the United States), Sanofi Aventis, U.S.'s claim that its business operations would come to a halt if it is forced to comply with the subpoenas "rings false." (*Id.*) As such, the MDL Plaintiffs argue that Sanofi-Aventis, U.S. will not be unduly burdened if forced to respond to the subpoenas and they should be ordered to produce the limited documents that the MDL Plaintiffs requested as well as the three witnesses for deposition.[1]

With respect to the witnesses they seeks to depose, the MDL Plaintiffs argue that their subpoenas issued to Wanju Dai, Drew Levy and Lourdes Frau are reasonable. The MDL Plaintiffs claim that the testimony of Drs. Dai, Levy and Frau "is crucial to understanding a number of issues pertaining to Levaquin, including the Ingenix Study and communications with the European regulatory agencies relating to levofloxacin." (*Id.* at 21). Specifically, the MDL Plaintiffs contend that Dr. Levy was the person in Sanofi-Aventis, U.S.'s "epidemiology department with day-to-day responsibilities for Levaquin during the time period Plaintiffs have an interest in." (*Id.* at 19). Further, the MDL Plaintiffs contend that they seek Dr. Frau's testimony because "Dr. Frau was one of the Sanofi employees who helped Johnson & Johnson develop the protocol for the study that became the 'Ingenix Study'" and because "Dr. Frau appeared to serve as a liaison between [the MDL] Defendants and Sanofi as the study's planning

[1]The MDL Plaintiffs have withdrawn the subpoena issued to Gaby Danan.

progressed." (*Id*. at 19-20). Similarly, the MDL Plaintiffs contend that their request to depose Dr. Dai is reasonable because as the discovery produced to date in this matter reveals, as an employee of Sanofi-Aventis, U.S., Dr. Dai "was critical in helping design and monitor the Ingenix Study." (*Id*. at 20).

The MDL Plaintiffs also argue that Sanofi-Aventis, U.S.'s demand that it be reimbursed for the costs incurred in responding to the subpoenas at issue is unreasonable. The MDL Plaintiffs claim that while Rule 45(c)(2)(B)(ii) requires an order to compel production to protect any person who is not a party from significant expense resulting from compliance with a subpoena, "[p]rotection from significant expense does not mean that the requesting party necessarily must bear the entire cost of compliance." (MDL Pls.' Opp'n Br. at 21). Here, the MDL Plaintiffs argue that the Court should not shift the cost of compliance because (1) Sanofi-Aventis, U.S., as "'part of a leading global pharmaceutical company'" (*Id*. at 22 (quoting http://www.sanofi-aventis.us/live/us/en/index.jsp.)) and the fifth largest pharmaceutical company in the United States is better able than the MDL Plaintiffs, all individuals "who suffer from various illnesses and injuries, some of which were caused by Defendants' drug[,]" to bear the cost of same (*Id*.); (2) Sanofi-Aventis, U.S. has a significant interest in the outcome of the MDL Action; and (3) the resolution of the MDL Action clearly is of public importance. In the alternative, the MDL Plaintiffs request that should the Court impose some fee-shifting, then it "set some parameters on the reasonable costs and fees and assist in determining the apportionment." (*Id*. at 23).

II. Analysis

A. Legal Standard

Pursuant to FED.R.CIV.P. 26(b), the scope of discovery in federal litigation is broad. In fact, "[parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense[.]" FED.R.CIV.P. 26(b)(1). Further, "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id*. The party resisting discovery bears the burden of establishing that discovery should not be had either because the information sought is not relevant or because even though relevant, a protective order is warranted. *See Guiterrez v. Johnson & Johnson, Inc.*, Civil Action No. 01-5302 (WHW), 2002 U.S. Dist. LEXIS 15418, at *10 (D.N.J. Aug. 12, 2002). Pursuant to FED.R.CIV.P. 26(c), where the resisting party has established good cause, the Court has discretion to issue a protective order that imposes limitations on the extent and scope of otherwise relevant discovery in order "to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense[.]"

Discovery sought via subpoenas issued in accordance with FED.R.CIV.P. 45 must fall within the scope of discovery permitted by Rule 26(b)(1). *See Schmulovich v. 1161 RT. 9 LLC*, Civil Action No. 07-597, 2007 WL 2362598, at *2 (D.N.J. Aug. 15, 2007) (citing *Transcor, Inc. V. Furney Charters, Inc.*, 212 F.R.D. 588, 591 (D. Kan. 2003)). If information sought via subpoena falls outside of the broad scope of discovery permitted by Rule 26(b)(1), then the Court

has authority to quash or modify the subpoena. FED.R.CIV.P. 45(c)(3). Indeed, pursuant to Rule 45(c)(3)(A)

> [o]n timely motion, the issuing court must quash or modify a subpoena that:
>
> (i) fails to allow a reasonable time to comply;
>
> (ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from were that person resides, is employed, or regularly transacts business in person . . . ;
>
> (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
>
> (iv) subjects a person to undue burden.

B. Relevance

Here Sanofi-Aventis, U.S. argues that the subpoenas at issue should be quashed because the information sought by the MDL Plaintiffs is irrelevant because any studies or communications it possesses regarding tendon disorders as they relate to fluoroquinolones concern the marketing of Tavanic in Europe by Sanofi-Aventis. Sanofi-Aventis, U.S. contends that testimony or documents concerning tendon disorders and their relationship with fluoroquinolones as they relate to the European market are irrelevant because in order to succeed on their claims against the MDL Defendants, the MDL Plaintiffs must establish that the MDL Defendants knew or should have known that Levaquin, a drug marketed and sold in the United States, was defective or unreasonably dangerous.

The Court disagrees with Sanofi-Aventis, U.S. While Sanofi-Aventis, U.S. is correct that in order to succeed in the MDL Action, the MDL Plaintiffs must prove that the MDL Defendants knew or should have known that Levaquin, a drug marketed and sold in the United States, was defective or unreasonably dangerous, it does not follow, as Sanofi-Aventis, U.S. suggests, that the MDL Defendants' knowledge concerning tendon disorders and their relationship to Tavanic,

a drug marketed and sold in Europe, is irrelevant to the MDL Plaintiffs' claims. Both Tavanic and Levaquin are brand names for the drug levofloxacin. Under the broad scope of discovery permitted by Rule 26(b), the MDL Defendants' knowledge concerning tendon disorders and their relationship to levofloxacin is relevant to the MDL Plaintiffs' claims regardless of whether the information at issue concerns the brand name Levaquin or Tavanic. As a result, the Court finds that the MDL Plaintiffs' requests for information pertaining to studies and/or communications concerning tendon disorders and their relationship to fluoroquinolones, of which levofloxacin is one, is relevant to their claims in the MDL Action.

C. Undue Burden

While the information sought in the subpoenas *ad testificandum* and *duces tecum* is relevant to the MDL Plaintiffs' claims in the MDL Action, pursuant to Rule 26(c), the Court may, nevertheless, prevent the MDL Plaintiffs from obtaining same in order to protect Sanofi-Aventis, U.S. from "annoyance, embarrassment, oppression, or undue burden or expense[.]" Further, pursuant to Rule 45(c)(3)(A), despite the relevance of the information sought, if the subpoenas at issue would subject Sanofi-Aventis to undue burden, then the Court must quash or modify same. A subpoena is considered unduly burdensome if the request for information is "'unreasonable or oppressive." *DIRECTV, Inc. v. Richards*, No. Civ. 03-5606 (GEB), 2005 WL 1514187, *2 (D.N.J. June 27, 2005) (quoting *Northrop Corp. v. McDonnell Douglas Corp.*, 751 F.2d 395, 403 (D.C. Cir. 1984)). The party moving to quash a subpoena bears the burden of proving that the subpoena is unreasonable or oppressive, and therefore unduly burdensome. *Id.*

A strict definition of an unreasonable or oppressive request does not exist; instead the Court must decide whether a subpoena is unreasonable or oppressive on a case by case basis.

OMS Inv., Inc. v. Lebanon Seaboard Corp., Civil Action No. 08-2681 (AET), 2008 WL 2362598, *3 (D.N.J. Nov. 18, 2008). In determining whether a subpoena is unreasonable or oppressive, the Court considers several factors including: (1) the party's need for the production; (2) the nature and importance of the litigation; (3) the relevance of the information sought; (4) the breadth of the request for production; (5) the time period covered by the request; (6) the particularity with which the documents are described; and (7) the burden imposed on the subpoenaed entity. *Schmulovich v. 1161 Rt. 9 LLC*, Civil Action No. 07-597 (FLW), 2007 WL 2362598, *4 (D.N.J. Aug. 15, 2007).

Here, the Court finds that Sanofi-Aventis, U.S. has established that despite the relevance of the information sought by the MDL Plaintiffs, the subpoenas at issue would subject Sanofi-Aventis, U.S. to undue burden. For example, while the MDL Plaintiffs attempt to limit the scope of the requested discovery by seeking primarily only two areas of information - information concerning tendon disorders and information concerning studies initiated at the request of European regulatory agencies that relate to fluoroquinolones - the Court finds the twelve-year time period covered by the subpoenas to be overly broad and unreasonable.

In addition, the Court does not believe that the MDL Plaintiffs have a significant need to obtain the information sought from Sanofi-Aventis, U.S. Instead, it appears that much of the information requested from Sanofi-Aventis, U.S. has or can be obtained from the MDL Defendants, Ingenix, the pertinent European regulatory agencies and/or Daiichi.[2] While the

[2]While the Court appreciates that Daiichi, like Sanofi-Aventis, U.S., is a non-party in the MDL Action, and therefore could theoretically object to subpoenas served upon it for similar reasons to those raised by Sanofi-Aventis, U.S., the Court finds that Daiichi as the owner of the patent for levofloxacin and the entity through which information concerning levofloxacin was typically communicated, not only likely possess the information sought by the MDL Plaintiffs

Court does not believe that the MDL Plaintiffs issued the subpoenas to Sanofi-Aventis, U.S. simply to confirm information already obtained or obtainable from these other sources, the duplicative and cumulative nature of the information sought from Sanofi-Aventis, U.S. supports the conclusion that the subpoenas are unreasonable or oppressive.

Similarly, the Court finds the MDL Plaintiffs request to depose three additional current/former Sanofi-Aventis, U.S. employees (Drs. Levy, Frau and Dai) to be unreasonable and oppressive.[3] While the Court appreciates that the underlying litigation is a multi-district litigation, the Court notes that under the Federal Rules of Civil Procedure, a party is typically limited to taking no more than 10 depositions. FED.R.CIV.P. 30(a). Here, the MDL Plaintiffs have already deposed Dr. Canabarro, a Sanofi-Aventis, U.S. employee. Indeed, Dr. Canabarro's deposition was continued for a second day. The MDL Plaintiffs now seek to depose three additional current/former Sanofi-Aventis, U.S. employees. In other words, the MDL Plaintiffs seek to take four depositions, nearly half of those typically permitted in discovery, from witnesses connected to Sanofi-Aventis, U.S., a non-party in the MDL Action. Moreover, while it appears that Drs. Levy, Frau and Dai possess information relevant to the MDL Plaintiffs' claims, it is equally apparent that their testimony will not only be duplicative and cumulative of much of each other's testimony but also of testimony that has been obtained or could be obtained from representatives of the MDL Defendants, Ingenix and Daiichi. As a result, the Court finds that it

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but is in a better position relative to Sanofi-Aventis, U.S. to produce same.

[3]The Court notes that while the MDL Plaintiffs initially sought to depose four additional individuals, they have since withdrawn the subpoena issued to Gaby Danan.

would be unduly burdensome to require Sanofi-Aventis, U.S. to produce all three additional individuals for deposition.

Further, while the Court does not believe that Sanofi-Aventis, U.S.'s business operations would come to a halt if compelled to comply with the subpoenas at issue, the Court does find that, despite its size, Sanofi-Aventis, U.S. would be burdened if forced to respond to same. Indeed, as explained above, given the broad time-frame encompassed by the subpoenas coupled with the duplicative nature of the documents and testimony requested and Sanofi-Aventis, U.S.'s prior compliance with the Canabarro Subpoena, the Court finds that it would be unduly burdensome for Sanofi-Aventis, U.S. to comply with the subpoenas at issue.

Given this undue burden, pursuant to Rule 45 (c)(3)(A)(iv), the Court must either quash or modify the subpoenas *ad testificandum* and *duces tecum* served on Sanofi-Aventis, U.S. After reviewing the parties' submissions, including their proposed modifications, the Court finds that the subpoenas need not be quashed in their entirety, but instead can be modified to eliminate the undue burden currently being imposed on Sanofi-Aventis, U.S. The Court shall therefore modify the subpoenas as follows: (1) the four document requests shall be limited in scope to the years 1999-2003; (2) with respect to the third document request, the MDL Plaintiffs shall provide Sanofi-Aventis, U.S. with a list of specific Johnson and Johnson employees for which Sanofi-Aventis, U.S. will search for all documents evidencing communications with same concerning tendon disorders as they relate to fluoroquinolones; (3) with respect to the fourth document request, the MDL Plaintiffs shall provide Sanofi-Aventis, U.S. with a list of specific Daiichi employees for which Sanofi-Aventis, U.S. will search for all documents evidencing communications with same concerning tendon disorders as they relate to fluoroquinolones; (4)

Sanofi-Aventis, U.S. shall produce Dr. Levy for a single, seven-hour day of testimony in accordance with Rule 30; (5) the subpoenas *ad testificandum* directed to Drs. Frau and Dai are quashed; and (6) Sanofi-Aventis, U.S. shall specifically search their records for emails sent to and from Drs. Frau and Dai concerning tendon disorders as they relate to fluoroquinolones. In accordance with FED.R.CIV.P. 34, Sanofi-Aventis, U.S. shall produce all responsive documents in its possession, custody or control.

D. Procedural Defects

In addition to the arguments discussed above, Sanofi-Aventis, U.S. also initially raised the following procedural grounds upon which it sought to quash the subpoenas at issue: (1) the MDL Plaintiffs improperly served a subpoena directed to Sanofi-Aventis on Sanofi-Aventis, U.S.; (2) in violation of Rule 45(c)(3)(A)(ii) the subpoenas require witnesses to travel more than 100 miles; (3) in violation of Rule 45(a)(2) the subpoenas were not issued from the Court for the District in which the depositions and production of documents are required to occur; and (4) in violation of Rule 45(b)(1), the subpoenas were not accompanied by witness and milage fees. The MDL Plaintiffs have since cured these deficiencies and as such these issues are now moot.[4]

E. Fee Shifting

According to Rule 45(c)(2)(B)(ii), an order compelling compliance with a subpoena "must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance." Thus the Court "must determine whether the subpoena imposes

[4]The Court notes that while the MDL Plaintiffs agreed to withdraw the subpoenas directed to Sanofi-Aventis and Gaby Danan, they argue that this does not prevent Sanofi-Aventis, U.S. from gathering documents from its European offices in order to respond to the remaining subpoenas. In this regard, the Court simply notes that, as stated above, Sanofi-Aventis, U.S. shall produce all responsive documents in its possession, custody or control.

expenses on a non-party and whether those expenses are significant." *R.J. Reynolds Tobacco v. Philip Morris, Inc.*, 29 Fed. Appx. 880, 883 (3d Cir. 2002). The language of Rule 45(c)(2)(B)(ii) is mandatory: "[s]ignificant expenses must be borne by the party seeking discovery." *R.J. Reynolds Tobacco*, 29 Fed. Appx. at 883; *see McCabe v. Ernst & Young, LLP.*, 221 F.R.D. 423, 425 (D.N.J. 2004) (noting that "[w]hen a court compels document production, it must protect a non-party from significant production expenses.") Nevertheless, "protection from significant expense does not mean that the requesting party necessarily must bear the *entire* cost of compliance[.]" *In re The Exxon Valdez*, 142 F.R.D. 380, 383 (D.D.C. 1992) (emphasis in original) (internal quotation marks omitted). Instead, factors such as "whether the non-party actually has an interest in the outcome of the case, whether the non-party can more readily bear its costs than the requesting party, and whether the litigation is of public importance" are relevant to "how much of the expense . . . the requesting party should bear[.]" *Id.*

In light of the Court's substantial modifications to the subpoenas issued to Sanofi-Aventis, U.S., coupled with the fact that the Court has no information regarding what Sanofi-Aventis, U.S.'s actual cost of responding to the modified subpoenas will be, the Court cannot find that responding to the subpoenas will result in significant expense. As a result, the Court does not, at this time, make any determinations regarding whether fee shifting in this matter is required and, if so, what portion of Sanofi-Aventis, U.S. cost in responding to the subpoenas must be borne by the MDL Plaintiffs in order to protect Sanofi-Aventis, U.S. from significant expense. After responding to the subpoenas, should Sanofi-Aventis, U.S. still believe that fee shifting under Rule 45(c)(2)(B)(ii) is appropriate, then it may make a fee application with this Court at that time.

III. Conclusion

For the reasons stated above, Sanofi-Aventis, U.S.'s motion to quash is granted in part and denied in part. The subpoenas issued to Sanofi-Aventis, U.S. are modified as outlined in Section II, C of this Opinion. An appropriate Order follows.

Dated: December 4, 2009

s/Tonianne J. Bongiovanni
HONORABLE TONIANNE J. BONGIOVANNI
UNITED STATES MAGISTRATE JUDGE